

**REMARKS**

Reconsideration of the subject application is respectfully requested.

1. **Amendments to Specification**

Applicants have amended the specification to address the noted informality at page 10, line 9. No new matter is introduced by way of the amendment to the specification.

Prompt entry of the proposed amendments is respectfully requested.

2. **Amendments to Claims**

Applicants have amended independent claim 1 to expressly recite that the complex fluid and the cooling fluid are distinct from each other. Support for this claim amendment is presented in the application, as filed (see, e.g., Fig. 4 and the accompanying text).

Independent claim 1 has also been amended to recite that a “cooling liquid” is provided to the system, support for which is presented in the application, as filed (see, e.g., page 21, line 5 *et seq.*) In addition, applicants have amended independent claim 1 to recite that the complex fluid is treated by the monochromatic light generated by the non-laser light source “at an energy level and for a period of time effective to inactivate at least one pathogen associated with the complex fluid.” Support for this amendment is also provided in the application, as filed (see, e.g., Examples beginning at page 37 of the specification). As such, no new matter is introduced by way of the proposed amendments to independent claim 1, and prompt entry thereof is respectfully requested.

Dependent claims 7 and 9 have been amended in a manner consistent with the foregoing amendments to independent claim 1.

Applicants have also amended independent claim 16 to recite that the bounded volume of photon-producing gas is “positioned within and spaced from a fluid-tight housing that includes at least one light emitting surface having a light emitting surface geometry.” Support for the proposed amendment to independent claim 16 is provided in the application, as filed (see, e.g., Fig. 4 and accompanying text). Accordingly, no new matter is introduced by way of the proposed amendment to independent claim 16, and prompt entry thereof is respectfully requested.

### 3. Election/Restriction

Applicants have canceled non-elected claims 10-15 and 22-32, without prejudice. Applicants expressly reserve the right to pursue the subject matter of the canceled claims by way of continuation and/or divisional patent filings and, consistent therewith, have filed a pair of divisional applications directed to non-elected subject matter.

### 4. Information Disclosure Statement

Applicants note that the Information Disclosure Statement re-filed on August 26, 2004, has now been reviewed in connection with examination of the present application. Applicants further note that the non-patent documents have not been considered because copies were not available to the Examiner. Applicants respectfully submit that copies of the non-patent publications were submitted to the Patent Office with applicants' initial IDS submission, and have been misplaced by the Patent Office. Accordingly, applicants respectfully submit that applicants' prior submission fully complies with applicants' duty of disclosure pursuant to 37 CFR § 56.

### 5. Claim Rejections –Section 102

In the outstanding Office Action, claims 1-2, 4-9 and 16-20 stand rejected under 35 USC §102(b) based on U.S. Patent No. 5,730,934 to Holbert (the “Holbert ‘934 patent”) or U.S. Patent No. 5,843,374 to Sizer et al. (the “Sizer ‘374 patent”). Reconsideration is respectfully requested.

As noted previously, the Holbert ‘934 patent is directed to a method/apparatus for sterilizing packaging through irradiation with an excimer ultraviolet lamp which may be integrated on a packaging machine. The excimer ultraviolet lamp emits radiation at a substantially monochromatic wavelength within the ultraviolet band of the electromagnetic spectrum. The excimer ultraviolet lamp is composed of a quartz shell containing one of the following gaseous compounds: Ar<sub>2</sub>, Kr<sub>2</sub>, Xe<sub>2</sub>, ArCl, KrCl, KrF or XeCl. In a disclosed embodiment of the Holbert ‘934 patent, the lamp has a central aperture through which cooling fluid is permitted to flow to remove heat from the lamp. If the excimer ultraviolet lamp is integrated on a form, fill and seal machine, the cooling fluid may additionally function as the content that is filled into a container fabricated on the form, fill and seal machine. However, in circumstances where the Holbert cooling fluid is used to fill the container, the cooling fluid is not treated/sterilized by excimer emissions from the lamp.

Also as noted previously, the Sizer ‘374 patent is directed to highly analogous subject matter relative to the Holbert ‘934 patent. As with the Holbert ‘934 patent, the Sizer ‘374 patent is directed to an apparatus for sterilizing packaging through irradiation with an excimer ultraviolet lamp which may be integrated on a packaging machine. The

excimer ultraviolet lamp emits radiation at a substantially monochromatic wavelength within the ultraviolet band of the electromagnetic spectrum. The excimer ultraviolet lamp is composed of a quartz shell containing a gaseous compound. As with the Holbert '934 patent, the Sizer '374 patent discloses an embodiment wherein the lamp includes a central aperture through which cooling fluid flows to remove heat from the lamp. In circumstances where the excimer ultraviolet lamp is integrated on a form, fill and seal machine, the Sizer '374 patent teaches that the cooling fluid may be the contents that are to be used in filling a container that is fabricated on the form, fill and seal machine. However, as with the Holbert '934 patent, in circumstances where the Sizer cooling fluid is used to fill the container, the cooling fluid is not treated/sterilized by excimer emissions from the lamp.

In advancing the current rejection based on the Holbert '934 patent and the Sizer '374 patent, the Examiner makes two statements of particular note:

- “Holbert teaches that the cooling material can be the desired contents for the container [citation omitted]. Sizer teaches this element at col. 7, lines 47-27 (sic)...” During this process, *both the milk and the carton are sterilized* and the milk serves as a heat sink for the light source (emphasis in original).”
- “Claims 1 and 16 do not recite a limitation that requires that the cooling fluid and the complex fluid are separate materials.”

With reference to the first statement quoted above, applicants find no basis in either the Holbert or the Sizer patent for the proposition that “both the milk and the carton are sterilized.” Indeed, a careful reading of both cited patents supports a contrary conclusion,

i.e., that only the container is sterilized (in conjunction with a sterilant, e.g., H<sub>2</sub>O<sub>2</sub>) by the Holbert and Sizer patents. To further emphasize this distinguishing aspect of applicants' presently claimed invention, applicants have amended independent claim 1 to recite that "said complex fluid [is] exposed to said monochromatic light at an energy level and for a period of time effective to inactivate at least one pathogen associated with said complex fluid." Moreover, independent claim 1 further recites that the cooling fluid is "effective to prevent said complex fluid from undergoing a temperature change damaging to said sensitive component." Thus, applicants' claimed system clearly distinguishes over the Holbert and Sizer patents in view of the complex fluid treatment recitations set forth herein.

With reference to the second quoted bullet set forth above, applicants respectfully submit that independent claim 1 previously provided that the complex fluid and the cooling fluid were distinct fluids: "said cooling fluid being effective to prevent said complex fluid..." However, applicants have amended independent claim 1 to expressly provide that the cooling fluid and the complex fluid are distinct fluids. Applicants respectfully submit that independent claim 1 further patentably distinguishes from each of the Holbert and the Sizer patents based on this express distinction.

In short, applicants reiterate their position that the Holbert and Sizer patents are directed to systems for sterilization of packaging, not complex fluids (e.g., milk), and that the Examiner's reliance on their teachings for "complex fluid treatment systems" is misplaced and without foundation. For at least the foregoing reasons, applicants respectfully submit that independent claim 1, as amended, patentably distinguishes over the Holbert '934 and Sizer '374 patents.

In like measure, dependent claims 2-9 (which depend directly from independent claim 1) patentably distinguish over the Holbert '934 and Sizer '374 patents for at least the reasons noted herein with respect to independent claim 1. Accordingly, reconsideration and withdrawal of the current rejection of claims 1-9 based on the Holbert '934 and Sizer '374 patents are requested.

Turning to independent claim 16, an advantageous system for treating complex fluids is provided that includes, *inter alia*, a fluid-tight housing that includes at least one light emitting surface having a light emitting surface geometry and a treatment surface having a treatment surface geometry, such that the foregoing geometries substantially correspond. Through a correspondence of the light emitting surface geometry and the treatment surface geometry, applicant's claimed treatment system of independent claim 16 is more effective and/or efficient.

Applicants have amended independent claim 16 to further distinguish the claimed subject matter from the Holbert and Sizer patents. More particularly, beyond the fact that the Holbert and Sizer patents do not define a treatment surface geometry, as disclosed and claimed by applicants, it is respectfully submitted that the references relied upon fail to teach or suggest a bounded volume of photon-producing gas that is positioned within and spaced from a fluid-tight housing that defines a light-emitting surface. Rather, the cited Holbert and Sizer patents contemplate photon-producing gases that are bounded by a structure that defines the outer housing. In other words, the cited patents fail to teach or suggest separating the structure that bounds the photon-producing gas from an external

housing that defines a light emitting surface having a light emitting geometry (which, in turn, substantially corresponds to a treatment surface geometry).

For at least the foregoing reasons, applicants respectfully submit that independent claim 16, as amended, patentably distinguishes over the Holbert and Sizer patents. Dependent claims 17-20 depend directly from claim 16 and patentably distinguish over the Holbert and Sizer patents for at least the reasons noted with respect to independent claim 16. Accordingly, reconsideration and withdrawal of the rejection of claims 16-20 based on the Holbert and Sizer patents are respectfully requested.

#### 6. Claim Rejections –Section 103

##### a. *Stinson '738 Patent in view of Eliasson '484 Patent*

In the outstanding Office Action, claims 1-6, 8, 9 and 16-20 are rejected under 35 USC §103(a) based on U.S. Patent No. 5,433,738 to Stinson (the “Stinson ‘738 patent”) in view of U.S. Patent No. 4,837,484 to Eliasson et al. (the “Eliasson ‘484 patent”). Reconsideration is respectfully requested.

The Stinson ‘738 patent is directed to a system/method for irradiating cells that pass through helically wound tubing positioned around a cylindrical housing that contains an ultraviolet light source. The Eliasson ‘484 patent teaches a waste water treatment system using a monochromatic light source that is cooled with a cooling liquid or a gaseous coolant. The Examiner takes the position that it would have been obvious to employ the light source of the Eliasson ‘484 patent for the light source of the Stinson ‘738 patent based on the overlap of wavelengths. The Examiner further takes the position that both light

sources are cooled, thereby further supporting the proposed combination. Applicants respectfully traverse the obviousness rejection.

First, in light of the fact that the Stinson '738 patent purportedly teaches a system that effectively irradiates cells, applicants respectfully submit that there would be no motivation to substitute the light source of the Eliasson '484 patent for the light source of the Stinson '738 patent (absent applicants' teaching), as proposed by the Examiner. The light source of the Eliasson '484 patent is directed to a system for use in treating waste water, an industrial application that certainly would not suggest to a person of ordinary skill in the art that the light source might be advantageous for treating complex fluids like blood. The fact that the two systems operate with overlapping wavelengths does not provide a basis for substituting one light source for another, given the significantly different characteristics of the light waves/energies produced thereby.

Moreover, the Stinson '738 patent teaches "ventilation" of its light source to "maintain a constant temperature in the apparatus 20 while the apparatus is in use." (See col. 8, line 19 *et seq.*) The disclosed ventilation system entails a "small duct fan 66, or other suitable source of air," for blowing air through an inlet port, etc. The Stinson '738 patent further teaches that "[i]t is to be understood that as an alternative to the duct fan 66, a vacuum or suction pump could be connected to the inlet port 64 in order to continuously ventilate the closed system." (See col. 8, lines 59-62.) Clearly, there would be no motivation to substitute a light source requiring greater cooling, as is apparently the case with the Eliasson '484 patent (based on its potential need for a cooling liquid), to treat sensitive materials such as cell suspensions.

Finally, the Examiner takes the position that ventilation of the lamp “inherently prevents the heat generated by the lamp from damaging a heat sensitive component of the blood being treated” and that “[t]he cooling is inherently sufficient to irradiate the cells without damaging its fluid components, otherwise the irradiated cells would be unsuitable for transplantation.” Applicants amended claim 1 recites a system wherein cooling is achieved with a cooling liquid. It is respectfully submitted that ventilation, as taught by the Stinson ‘738 patent, would be ineffective to prevent damage to a complex fluid using applicants’ claimed light source, particularly given the difference in energy delivery contemplated by the two systems [cf., Stinson: approx. 150 J/m<sup>2</sup> (col. 10, lines 57-68); applicants: >4 J/cm<sup>2</sup> (page 37, line 19 *et seq.*)].

For at least the foregoing reason, applicants respectfully submit that the cited references, whether taken alone or in combination, fail to teach or suggest a treatment system as recited in applicants’ independent claim 1 that includes, *inter alia*, “a non-laser light source for generating and transmitting substantially monochromatic light” and “a cooling liquid in thermal communication with the light emitting surface,” such that the cooling liquid is “effective to prevent the complex fluid from undergoing a temperature change damaging to the sensitive component.” Indeed, the cited references effectively teach away from the claimed invention by suggesting that an altogether different light source – which is cooled by ventilation air – is effective to irradiate cell suspensions, while a light source of the type disclosed and claimed by applicants finds utility in industrial applications. Nothing in the cited references would motivate a skilled artisan to: (1) undertake to treat complex fluids (e.g., blood or vaccines) with a monochromatic light,

and/or (2) direct a cooling liquid to the light emitting surface in a manner that ensures that the complex fluid does not suffer temperature-related damage. Dependent claims 2-9 patentably distinguish over the cited references for at least the reasons noted with respect to independent claim 1. For at least these reasons, applicants request reconsideration and withdrawal of the outstanding obviousness rejection of claims 1-9.

Turning to independent claim 16, applicants respectfully traverse the examiner's obviousness rejection because, *inter alia*, the Stinson '738 patent fails to teach or suggest a system that includes a light source for generating monochromatic light, wherein a light emitting surface geometry "substantially corresponds" to a treatment surface geometry. Indeed, the helically wound tubing of the Stinson '738 patent defines an arcuate outer surface which cannot substantially correspond to the oppositely radiused outer cylinder 22. As noted above, there is no motivation to combine the teachings of the Stinson 738 patent with the Eliasson '484 patent so as to substitute the Eliasson light source. Moreover, if such combination were made, the fluid to be treated would flow through helically wound tubing, which would not satisfy the "substantially corresponding" geometries of applicants' claim 16. The Examiner is not permitted to pick and choose from the references to arrive at applicants' claimed invention. Accordingly, reconsideration and withdrawal of the outstanding obviousness rejection of claims 16-20 are earnestly solicited.

*b. Stuhl '513 Patent in view of Stinson '738 Patent, Eliasson '484 Patent and Hartman '537 Patent*

In the outstanding Office Action, claims 1, 2, 5-9 and 16-21 are rejected under 35 USC §103(a) based on U.S. Patent No. 3,986,513 to Stuhl (the "Stuhl '513 patent") in view

of the Stinson '738 patent, the Eliasson '484 patent, and U.S. Patent No. 6,447,537 to Hartman (the "Hartman '537 patent). Reconsideration is respectfully requested.

The Stuhl '513 patent is directed to an apparatus for treating skin for psoriasis. The Stuhl device generates UV light from a lamp that is cooled with circulating air. The Stuhl '513 patent is deficient in several respects, including its teaching with respect to a different light source, a different (and inadequate) cooling system relative to applicants' claimed invention, and a failure to teach/suggest inactivation of at least one pathogen in a complex fluid, as required by applicants' amended claim 1. The secondary references fail to cure the above-noted deficiencies. Specific shortcomings of the Stinson and Eliasson patents are discussed above. The Hartmann '537 patent does nothing to cure these deficiencies.

Simply stated, there is no motivation to pick and choose from among these four patents – two for psoriasis treatment, one for treatment of cell suspensions and one for treatment of waste water – to arrive at a system that meets the requirements of applicants' amended claim 1. Indeed, the two psoriasis disclosures would be ignored by a skilled artisan attempting to inactivate at least one pathogen in a complex fluid. For at least the foregoing reasons, the proposed combination of the Stuhl '513 patent, the Stinson '738 patent, the Eliasson '484 patent and the Hartman '537 patent is ineffective and fails to render obvious independent claim 1. Dependent claims 2 and 5-9 patentably distinguish over the proposed combination for at least the reasons noted with respect to independent claim 1.

With reference to independent claim 16, the Stuhl '513 patent simply does not teach a light source that generates monochromatic light, nor does it contemplate a structural arrangement wherein the "light emitting surface geometry substantially corresponds to [the] treatment surface geometry." The shortcomings of the Stinson and Eliasson patents with respect to independent claim 16 were previously discussed. The teachings of the Hartman '537 patent fail to cure such deficiencies. For at least these reasons, independent claim 16 (and claims 17-21 which depend therefrom) patentably distinguish over the proposed combination of references.

For the foregoing reasons, applicants respectfully submit that all pending claims are in condition for allowance. Prompt action leading to an early notice to this effect is earnestly solicited. If the examiner believes a telephone conversation with applicants' undersigned representative may assist in advancing prosecution of this application, he is invited to contact the undersigned counsel at the noted number.

Respectfully submitted,



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